DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 16, 2014

Transonic Systems, Inc.
Naveen Thuramalla
VP, Engineering & Clinical Studies
34 Dutch Mill Rd
Ithaca, New York 14850

Re: K140017
Trade/Device Name: Transonic HCM102 System
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG
Dated: June 17, 2014
Received: June 18, 2014

Dear Naveen Thuramalla,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

transonic
THE MEASURE OF BETTER RESULTS.

Transonic Systems Inc.
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Indications for Use

510(k) Number (if known): New Submission

Device Name: Transonic HCM102 System

Indications for Use: (Prescription Device)

The Transonic HCM102 system is intended for diagnostic assessment of cardiovascular status and circulatory variables in patients aged 1 month and older. This includes COstatus measurements by indicator dilution for quantifying patient's cardiac and volume status as well as continuous cardiac output and associated hemodynamic parameters (such as stroke volume variation; pulse pressure variation, systemic vascular resistance and related index parameters) by continuous arterial pressure waveform analysis. In this system, cardiac output (CO) value from dilution is used to calibrate the pressure wave form and assess continuous cardiac output. In addition the system also measures heart rate, systolic, diastolic pressures, mean arterial pressure and indexed parameters.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) SUMMARY

Summary of Safety & Effectiveness

Submitter's Name & Address: Transonic Systems Inc
34 Dutch Mill Road,
Ithaca, NY 14850

Contact Person & Telephone: Naveen Thuramalla
607-257-5300 (*326)

Date Summary Prepared: Dec 30, 2013

Device Name: Classification Name: Computer, Diagnostic, Pre-programmed, Single-function, 21 CFR 870.1435.
Product Class and Code: DXG and Class II
Classification Panel: Cardiovascular
Common/Usual Name: Extracorporeal, Diagnostic monitor
Proprietary Name: Transonic HCM102 System

Predicate Devices: K060898: PULSION PICCO PLUS, MODEL 8100.

K023960: LIDCOPLUS HEMODYNAMIC MONITOR SYSTEM, MODEL HM 70.

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, Transonic Systems Inc. intends to introduce into interstate commerce the Transonic HCM102 system, which is an apparatus based on ultrasound dilution and arterial pressure waveform analysis to provide diagnostic assessment of cardiovascular status including COstatus (HCM101) measurements by indicator dilution for quantifying patient's cardiac and volume status as well as continuous cardiac output and associated hemodynamic parameters (such as stroke volume variation; pulse pressure variation, systemic vascular resistance and related index parameters) by continuous arterial pressure waveform analysis. In this system, cardiac output is first measured by COstatus (HCM101) system and this is then automatically transferred to calibrate the

arterial pressure waveform to obtain continuous cardiac output (when that mode is selected). Thus cardiac output is determined both intermittently through ultrasound technique and continuously through arterial pressure waveform analysis. In addition the system also measures heart rate, systolic, and diastolic pressures and derives mean arterial pressure. These patients could be in the intensive care units (ICU), operating room (OR) or other such environments.

Components:

Transonic HCM102 system consists of the following components. The below components are essentially COstatus system components with the addition of pressure transducer and connecting cable.

Model/Part #	Description
HCM102	Monitor (HCM101 monitor with the addition of pressure capability)
HCM101	Cardiac output monitor/meter
HC2TP	Flow/dilution sensor pair with pump cable and pressure transducer cables.
HCP01	AV Loop Pump
ADT2005D	Arteriovenous (AV) Loop – Tubing Set
ADT2005E	Arteriovenous (AV) Loop – Tubing Set
ADT2006E	Arteriovenous (AV) Loop – Tubing Set
ADT1020	Extension Set/ Sensor Adapter Tubing
HCS3011	AV Loop kit with ADT2005D AV Loop
HCS3021	AV Loop kit with ADT2005E AV Loop
HCS3022	AV Loop kit with ADT2006E AV Loop
HCS3002	Sensor Adapter Tubing Pack with ADT1020
HCS40XX	MX950 TranStar Disposable Transducer (K061573) or equivalent.
HCR01	Printer
HFW1000	Fluid Bag Warner
HCED02	Data Transfer Module
HCR01	Printer

Substantial Equivalence:

The Transonic HCM102 System for use with patients to provide diagnostic assessment of cardiovascular status including intermittent and continuous cardiac output and associated hemodynamic parameters (such as total end diastolic blood volume, central blood volume, active circulation volume, stroke volume variation; pulse pressure variation, etc) is similar to the Pulsion Continuous Pulse Contour Cardiac Output (PiCCO Plus) System (K060898) and LiDCO plus monitor (K023960).

Proposed device and predicate devices first measure cardiac output and other related hemodynamic parameters intermittently and then use the intermittent Cardiac output to calibrate the arterial blood pressure waveform to measure continuous cardiac output. Arterial blood pressure waveform is also analyzed to obtain other related hemodynamic parameters such as stroke volume variation and pulse pressure variation. All three systems are extracorporeal in nature and use both indicator dilution as well as arterial pressure waveform approaches. All three would require access to both arterial and central venous catheters to obtain indicator dilution and arterial pressure waveform measurements.

The difference between Pulsion PiCCO Plus system and the proposed HCM102 system is that the Pulsion system requires use of a dedicated special arterial catheter insertion into the patient, which is then connected to the Pulsion monitor for both types of measurements. However, Transonic HCM102 system works off an extracorporal AV tubing set connected between standard in-situ arterial and central venous lines (like COstatus system cleared by FDA K113821) for indicator dilution measurements and requires connecting a standard pressure transducer (such as MX950 or equivalent cleared by FDA K942377) in-line with the hospital pressure transducer for arterial pressure waveform measurements.

Pulsion system uses thermodilution and hence requires injection of cold or room temperature isotonic saline whereas Transonic HCM102 system uses ultrasound dilution and hence requires injection of body temperature isotonic saline.

The difference between LiDCPlus hemodynamic monitor and the proposed HCM102 system is that the LiDCO plus monitor uses lithium dilution, which requires injection of lithium, is used to obtain intermittent dilution cardiac output measurement and other related parameters. Transonic HCM102 system works off an extracorporal AV tubing set, which is connected between standard in-situ arterial and central venous lines (like COstatus system cleared by FDA K113821), and uses body temperature isotonic saline to obtain intermittent dilution cardiac output measurement and other related parameters.

For continuous arterial pressure waveform measurements, LiDCO Plus monitor uses the analogue arterial blood pressure trace that is slaved from the conventional blood pressure monitor to produce continuous arterial pressure waveform measurements while in case of Transonic HCM102 system a standard pressure transducer (such as MX950 or equivalent cleared by FDA K942377) is connected in-line with the hospital pressure transducer for continuous arterial pressure waveform measurements.

These differences do not raise any new issues of safety or effectiveness regarding the use of Transonic HCM102 System.

Safety and Effectiveness:

The HCM102 is deemed to be safe and effective based on the safety testing conducted in accordance with the IEC 60601-1 standard and the electromagnetic compatibility test report.

In addition, bench and animal testing was conducted by Transonic Systems Inc. and the test reports can be found in Section 18 and Section 19 of this 510(k) submission. Prior to shipment, the finished product will be tested and must meet all required release specifications before distribution. The array of testing required for release includes, but are not limited to; physical testing and visual examination (in-process and finished product). The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures that ensure the product's performance parameters conform to the product design specifications. The testing instruction records for each of the individually required procedures are approved, released, distributed, and revised in accordance with document control cGMP's.